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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,730	07/14/2003	Nicholas deBeer	TSNMNE00100	1584

40518 7590 11/24/2009

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EXAMINER	
SWEET, THOMAS	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,730	DEBEER, NICHOLAS	
	Examiner	Art Unit	
	Thomas J. Sweet	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-43 and 50-69* is/are pending in the application.

4a) Of the above claim(s) *69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-43 and 50-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/30/2009* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 06/30/2009 have been fully considered but they are not persuasive. Regarding the 112 rejection, [0094] does not support a target conforming to a shape having both porous areas engaging a surface. The passage has both conforming and two porous area but as applicant argues on 09/15/2008 each of the porous area must engage the target (i.e. conform to the surface). Since, the device does not engage target in areas there must be a clear teaching to one of skill in the art that each of these porous surfaces engage the target surface. Without this teaching one of skill could not recognize this as a patentable feature at the time the invention was file. Regarding 103-I, the motivation is clearly set out in the rejection. In fact it is the same motivation as the based reference (plus an additional motivation) so it is mere substitution of an equivalent in the art with the added feature of allowing medication to migrate out. Applicant further attempts to argue that the combination would not work is not supported as required by facts (merely arguments). It is within the skill level of one of ordinary skill in the art could make the low pressure passage of saline to work in the invention, especially since it is saline passing out of both devices. Regarding 103-II, the Examiner would like to point out the final product is solid so it is clearly of interest to reinforce the final product. Regarding 103-III, the examiner would like to point out that its not destroying a reference when the final product meets the intention of the reference. The substitution in that art isn't to render the balloon of Chobotov non fluid tight, it is fill the balloon with a curing fluid to expand and seal the balloons of Chobotov in a ridged fashion (an seals the pores) rather than with merely a fluid that could lose pressure and not secure the body to the target.

Election/Restrictions

Newly submitted claim 69 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new features in claim 69 are covered by non elected species of for example G and H (fig. 34-45).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 69 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-43, and 50-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendments to 34 and 59 include "first and second surfaces that each engage and conform to respective first and second portions of the target" the first and second surfaces have different porosities. There is nothing in passages [0007], [0013], [0102] and [0114] or other passages found by the Examiner that supports the surfaces of different porosities each engaging the target. That is, not all of the surfaces necessarily engage the target and nothing of

record appears to support that the surfaces of different porosities necessarily engage and conform to the target so one of ordinary skill would not recognize this as the inventive feature.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (US 6,547,804) in view of Strother et al (US 4364392). Porter et al. discloses a method of providing an encapsulation device to a desired location (figs. 1a-6), the method comprising; expanding a porous body (fig. 2) to conform (to be or become similar in form or character) to a shape of a target (an aneurysm) by introducing a first fluid (saline, 30) into an opening in the body (25), where the porous body comprises at least a first and second surface that engage and conform to respective first and second portions of the target, where;

introducing a second fluid (32, solidifying/adhesive) into the porous body to displace the first fluid through the pores; and

allowing the second fluid to cure to secure the porous body to the target (fig. 6).

However, Porter et al remains silent as to the first surface has permeability different than a second surface of the porous body so that displacing the first fluid at least the first surface of the porous body is different than the second surface of the porous body.

Strother et al teaches another method of providing an encapsulation device (fig. 8) to a desired location (e.g. fig. 2 or 7) including to the first surface (72) has a permeability different

than a second surface (71) of the porous body so that displacing the first fluid (carrier fluid) at least the first surface of the porous body is different than the second surface of the porous body (col 6, lines 47-55) for the purpose releasing the carrier fluid (such as the saline 30 or solvent) from the balloon and to allow medication to migrate out. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a first surface has a permeability different than a second surface of the porous body so that displacing the first fluid at least the first surface of the porous body is different than the second surface of the porous body as taught by Strother et al on the pore balloon of Porter et al in order to release the saline and/or solvent and allow medication to migrate out.

With regard to claims 35-37, the step of inserting a wire reinforcement into the porous body, securing the wire reinforcement to the interior of the porous body, and removing the wire reinforcement from the porous body (col 3-4, lines 42-15).

With regard to claim 38, Porter et al remains silent as to specifically using (ePTFE) or (PET). It is admitted prior art that surgical balloons use (ePTFE) or (PET) for the purpose of providing a biocompatible balloon material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute (ePTFE) or (PET) for the balloon material of Porter et al since they are biocompatible and such a modification amounts to mere substitution of one functionally equivalent balloon material for another within the art of surgical balloons.

With regard to claim 43, the second fluid is more viscous than the first fluid (inherent since the first fluid displaces the second).

Claims 52-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al in view of Soltesz et al (US 6527761). Porter et al discloses a method of providing an encapsulation device to a desired location, the method comprising:

expanding a porous body to conform to a shape of a target by introducing a first fluid into an opening in the body;

introducing a second fluid into the porous body to displace the first fluid through the porous body; and

allowing the second fluid to cure to secure the porous body to the target such that the wire reinforcement remains within the porous body (discussed above).

However, Porter et al does not disclose securing a wire reinforcement to an interior surface of the body to assist the body in maintaining the shape. Soltesz et al discloses another encapsulation device (title) including a wire reinforcement (col 3, lines 16-19) to an interior surface of the body (col 3, lines 25-27) for the purpose of assist the body in maintaining the shape (col 3, lines 27-29). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a wire reinforcement as taught by Soltesz et al in the body of Porter et al in order to assist the body in maintaining the shape.

With regard to claim 53, Porter et al remains silent as to specifically using (ePTFE) or (PET). It is admitted prior art that surgical balloons use (ePTFE) or (PET) for the purpose of providing a biocompatible balloon material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute (ePTFE) or (PET) for the balloon material of Porter et al since they are biocompatible and such a modification amounts to mere

substitution of one functionally equivalent balloon material for another within the art of surgical balloons.

Claims 34-51, 59-61 and 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chobotov (US 6395019) in view of Porter et al and Strother et al. Chobotov discloses a method of providing an encapsulation device (fig. 4) to a desired location, the method comprising:

expanding a body (fig. 4) to conform to a shape of a target (vessel) by introducing a first fluid into an opening in the body (33) where the body comprises at least one rib (55) on an exterior surface of the body (fig. 4) and having a larger diameter than the body when expanded (as shown), where expanding the body to conform to the shape mechanically locks the rib against the target (vessel).

However, Chobotov does not discloses the body as porous and introducing a second fluid into the porous body to displace the first fluid through the at least the first side of the porous body differently than the second side of the porous body; and allowing the second fluid to cure to secure the porous body to the target.

Porter et al teaches another encapsulation device including an inflatable porous body and introducing a second fluid into the porous body to displace the first fluid through the at least a first side of the porous body and allowing the second fluid to cure for the purpose secure the porous body to the target.

Strother et al teaches another encapsulation device including an inflatable porous body with surfaces of different porosity for the purpose of allowing carrier fluid (i.e. solvents) to be release.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the inflatable porous material of Porter et al for the inflatable portions (55) of the body of Chobotov and utilizing a second curing fluid in order to secure the body to the target (in order not to destroy the Chobotov reference only the inflatable portions, 55 are substituted so that Chobotov would still function as a graft allowing the carrier fluid to release as taught by Strother et al) and as such the second side (inner lumen) of the porous body (fig. 4) would not be permeable.

With regard to claim 60, further comprising the step of inserting a wire reinforcement (66) into the porous body (fig. 4).

With regard to claim 61, further comprising the step of securing the wire reinforcement (66) to the interior of the porous body (such as shown in fig. 3).

With regard to claim 63, Porter et al remains silent as to specifically using (ePTFE) or (PET). It is admitted prior art that surgical balloons use (ePTFE) or (PET) for the purpose of providing a biocompatible balloon material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute (ePTFE) or (PET) for the balloon material of Porter et al since they are biocompatible and such a modification amounts to mere substitution of one functionally equivalent balloon material for another within the art of surgical balloons.

With regard to claims 66-68, Porter et al discloses these limitations as discussed above.

Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chobotov in view of Porter et al and Strother et al as applied to claim 59 above, and further in view of Aboul-Hosn (US 6,976,996). Chobotov as modified discloses a method of providing an

encapsulation device (as discussed above). Chobotov as modified does not discloses the step of removing the wire reinforcement from the porous body. Chobotov does disclose using a balloon catheter to removably reinforce the body during deployment (col 5, lines 51-59). It is well known in the art of balloon catheters to including reinforcing wire for the purpose of preventing kinks as demonstrated by Aboul-Hosn (fig. 20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wire reinforcement in the catheter or substitute the balloon catheter of Aboul-Hosn for the balloon catheter of Chobotov in order to prevent kinks. Such a modification would include a step of inserting a wire reinforcement (in the reinforcing balloon) into the porous body (fig. 4), securing the wire to the body by via the balloon and removing a wire reinforcement once the body is deployed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/
Primary Examiner, Art Unit 3774